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**Datasheet for the decision  
of 25 September 2008**

**Case Number:** T 1014/06 - 3.2.02

**Application Number:** 97927576.5

**Publication Number:** 0910425

**IPC:** A61M 25/00

**Language of the proceedings:** EN

**Title of invention:**  
Catheter package

**Patentee:**  
Astra Tech AB

**Opponent:**  
Coloplast A/S

**Headword:**  
-

**Relevant legal provisions:**  
EPC Art. 52, 56

**Keyword:**  
"Inventive step - (yes)"

**Decisions cited:**  
-

**Catchword:**  
-



Case Number: T 1014/06 - 3.2.02

**DECISION**  
of the Technical Board of Appeal 3.2.02  
of 25 September 2008

**Appellant:** Coloplast A/S  
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**Representative:** Frederiksen, Jakob Pade  
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**Respondent:** Astra Tech AB  
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**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 2 May 2006  
rejecting the opposition filed against European  
patent No. 0910425 pursuant to Article 102(2)  
EPC.

**Composition of the Board:**

**Chairman:** T. Kriner  
**Members:** D. Valle  
M. J. Vogel

## Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal on 30 June 2006 against the decision of the opposition division posted on 2 May 2006 to reject the opposition. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 12 September 2006.
- II. The patent was opposed on the basis of Article 100 (a) EPC (lack of novelty and inventive step) and 100 (b) EPC (insufficient disclosure). However, the opposition division held that the patent in suit meets the requirements of the EPC.
- III. The following documents are relevant for the present decision:
- D1 = GB - A - 2 131 384  
D4 = US - A - 3 939 971  
D11 = EP - A - 217 771  
D15 = US-A-5334166  
D16 = US-A-5416131  
D17 = J. D. Smart et al., "An in-vitro investigation of mucosa-adhesive materials for use in controlled drug delivery", J. Pharm. Pharmacol, 1984, 36, 295 - 299.
- IV. Oral proceedings have been held on 25 September 2008.
- The appellant requested that the decision under appeal be set aside and that the patent be revoked.
- The respondent (patentee) requested that the appeal be dismissed.

V. Claim 1 as granted reads as follows:

"A catheter package comprising a surface coated catheter (1; 101; 201) and an inner container (2; 102; 202) which encloses the catheter (1; 101; 201) and permits the passage of a sterilizing agent for the catheter therethrough, the package further comprising an outer container (3; 103; 203) which encloses the inner container (2; 102; 202) characterized in that said outer container comprises a material forming a moisture barrier, whereby the outer container (3; 103; 203) prevents or substantially prevents access of moisture to the interior of the outer container."

VI. The appellant argued essentially as follows.

The subject-matter of claim 1 did not involve an inventive step.

The most relevant state of the art was represented by D1. This document disclosed all features of the preamble of claim 1, except the one according to which the catheter was a surface coated catheter. The characterising portion of claim 1 merely required that the outer container comprised a material forming a moisture barrier which was not necessarily a perfect moisture barrier, as could be concluded from the words "substantially prevents access of moisture".

Since the paragraph bridging columns 1 and 2 of D1 described that at least one face of the outer container was made of plastic material, and since plastic material inevitably formed a moisture barrier, D1 also disclosed the characterising features of claim 1.

If the board concluded that the characterising features of claim 1 were not disclosed in D1, the object to be achieved could be regarded as to modify the known package so that it was also suitable for surface coated catheters.

Documents D15, D16 and D17 showed that it was well known that friction reducing coatings as used on catheters were sensitive to moisture. Hence it was obvious for the skilled person to modify the package according to D1 so that access of moisture was prevented, and it was also obvious that this could be done by providing an outer container which formed a moisture barrier, as for example shown in D4.

Alternatively, starting from D11 which disclosed a coated catheter, it was obvious to provide a moisture tight package as suggested by D4 in order to overcome the problem that the coating of the catheter could become sticky in the presence of moisture, in particular when considering Figure 3 and the statement in column 1, lines 33 to 35 about the deleterious effect of water vapour. Since coatings for catheters were all more or less sensitive to water, as also pointed out in the paragraph 0019 of the patent in suit, the problem of protecting such coatings from moisture was an obvious problem to be solved.

VII. The respondent contested the statements of the appellant and argued essentially as follows.

The subject-matter of claim 1 was based on an inventive step. The outer container as suggested by D1 was not suitable to form a moisture barrier. On the contrary,

D1 explicitly described (see description, lines 97 - 107) a gas permeable paper back face of the outer container. Hence the skilled person had no reason to modify the outer container of D1 in such a way that it became moisture tight, in particular since D1 did not mention the purpose of the present invention of preventing the catheter coating from becoming sticky. Column 1, line 40 of D1 merely disclosed that the inner envelope could stick to its content after long storage. However, that did not mean that the catheter coating could become sticky.

D4 was concerned with packaging of surgical instruments to be sterilized and was far away from the field of the invention. Therefore, the skilled person would not have taken D4 into consideration.

D11 did not refer to a catheter package and therefore was not suitable to be considered as representing the closest state of the art.

## **Reasons for the Decision**

1. The appeal is admissible.
2. *The state of the art*
  - 2.1 D1 discloses a catheter package comprising a catheter (1) and an inner container (4) which encloses the catheter and permits the passage of a sterilizing agent for the catheter therethrough, the package further comprising an outer container (3) which encloses the inner container.

However, D1 does not disclose that

- i) the catheter is surface coated, and
- ii) that said outer container comprises a material forming a moisture barrier, whereby the outer container prevents or substantially prevents access of moisture to the interior of the outer container.

The appellant's arguments that D1 discloses the feature ii) are not convincing. It is true that D1 discloses an outer container, at least one face of which is of a plastic material. However this does not mean that the outer container prevents or substantially prevents access of moisture to its interior. D1 merely requires that the plastic material is transparent. However, it does not require that the plastic material is provided to form a moisture barrier. On the contrary, the preferred embodiment described in column 2, lines 98 to 103 of D1 requires the presence of a gas-permeable paper back for the outer container in order to allow permeation of sterilizing gases.

- 2.2 D4 (see in particular Figure 3) discloses a package for medical or surgical implements which may be sterilized at a time and location remote from the packaging thereof. For this purpose the package comprises an outer container (114, 116) impervious to the sterilizing gas and an inner container (118) pervious to this gas but substantially impervious to water vapor in order to prevent rust formation on metallic implements.

2.3 D11 refers to a coated catheter, and D15 to D17 show that friction reducing coatings, as for example used on coated catheters, are sensitive to moisture.

3. *Inventive step*

3.1 Starting from D1 the object to be achieved by the patent in suit may be regarded as to provide a package for a coated catheter which avoids that the coating is damaged, destroyed or mutilated (see column 1, lines 45 to 49 of the patent in suit).

This object is achieved by features i) and ii) mentioned in paragraph 2.1 above.

It is conceded that coated catheters were well known before the priority date of the patent in suit (see for example D11). Furthermore, it was also known that a friction reducing coating is sensitive to moisture (see D15 to D17). However, this does not mean that the skilled person would consider to use the package according to D1 for coated catheters, let alone to modify this package so that the outer container prevents or at least substantially prevents access of moisture to its interior. On the contrary, since the complete teaching of D1 is directed to a package which allows permeation of a sterilizing gas to the interior of the outer container, which is exclusively achieved by the provision of a gas-permeable paper back face, the provision of a moisture tight outer container without the paper back face would be against the teaching of D1. Hence the skilled person had no reason for modifying the package of D1 in order to solve the object to be achieved.



Accordingly, the subject-matter of claim 1 involves an inventive step starting from the teaching of D1.

- 3.2 Starting from D11, the problem to be solved could be seen in providing a suitable package for a surface coated catheter.

The appellant's argumentation according to which the skilled person would obviously select the package as described in D4 is not convincing. Since D4 does not refer to a package for coated implements such as catheters, and does not even mention the problem of moisture sensitivity of coatings, there is no sensible reason that would lead the skilled person to consider the teaching of D4 for packaging the catheter of D11.

Accordingly, the subject-matter of claim 1 also involves an inventive step against a combination of the teaching of D11 and D4.

**Order**

**For these reasons, it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

T. Kriner